

ACC-i2 with TCT

THE REMEDEE STUDY: INSIGHTS FROM THE ANGIOGRAPHIC AND INTRAVASCULAR ULTRASOUND COMPARISON OF A COMBINATION SIROLIMUS ELUTING EPC CAPTURE STENT WITH A PACLITAXEL ELUTING STENT

i2 Poster Contributions
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Background: REMEDEE is a randomized, multicenter study comparing the Combo Bio-engineered Sirolimus Eluting Stent(OrbusNeich Medical, Ft. Lauderdale, FL, USA) to the Taxus® Liberté® Paclitaxel Eluting Coronary Stent (Boston Scientific, Natick, MA, USA). The primary study endpoint is angiographic late lumen loss (LLL) at 9 months assessed for non-inferiority.

Methods: All patients consented to angiographic follow up at 9 months and a subgroup consented to intravascular ultrasound(IVUS)follow up too. Independent Core Laboratories assessed the angiographic and IVUS data.

Results: The mean angiographic LLL of Combo was non-inferior to Taxus ($0.39\pm0.45\text{mm}$ for Combo vs. $0.44\pm0.56\text{mm}$ for Taxus; $p=0.55$), however LLL distributions showed different patterns with Combo showing a slight tail and Taxus exhibited a bimodal nature. Although not powered for superiority in angio and IVUS parameters, these observations coincided with a 43% reduced restenosis rate (5.5% in Combo vs. 9.6% for Taxus; $p=0.34$) and a 45% reduced clinically driven Target Lesion Revascularization (5.2% for Combo vs. 9.5% for Taxus; $p=0.35$). The IVUS follow up showed a 17% reduction in neointimal (NI) volume ($21.53\pm21.71\text{mm}^3$ for Combo vs. $25.95\pm18.65\text{mm}^3$ for Taxus; $p=0.50$). IVUS imaging showed homogeneous NI with Combo contrasted with heterogeneous NI from Taxus.

Conclusions: While Combo was found non-inferior in LLL to Taxus, quantitative and qualitative differences were observed in patterns of LLL assessed by QCA and NI by IVUS.

